REMARKS

Status of the claims

Claim 1-19 are pending in this application. Claims 11-19 have been withdrawn from consideration by way of a restriction requirement. (Office Action at item 1) Claims 1-10 stand rejected. Amendments to the claims presented herein introduce no new matter. Amendments were made primarily to convert from a European-style claim language to U.S.-style and to clarify the claims.

Sequence compliance

A new Sequence Listing is provided that includes the sequence shown in claim 4. This was added to the previous Sequence Listing at the Examiner's request for Sequence Compliance. (Office Action at item 2) No new matter appears in this replacement Sequence Listing.

Objection to the Specification

The Examiner has objected to the specification for the presence of legal phraseology. (Office Action at item 3) The Abstract has been amended accordingly. Withdrawal of this objection is respectfully requested.

Information Disclosure Statement

The Examiner has requested titles for non-patent literature articles cited. (Office Action at item 4) Applicant's are submitting new IDS with the titles.

Claim Objections

Claim 10 has been objected to for being a multiply dependent claim dependent from another multiply dependent claim. (Office Action at item 5) Claim 10 has been amended to remove this improper dependency. Withdrawal of this objection is respectfully requested.

Rejections under 35 U.S.C. §§112/101

The Examiner has rejected claims 1-10 for being indefinite under 35 U.S.C. §112, second paragraph and for failure to have proper format under 35 U.S.C §101 for a method claim. (Office Action at items 8 and 9. More specifically, at issue here is the lack of clarity as to whether the claims are method claims (which improperly recite no active steps) or composition claims. Applicant's

clarify, by way of amendment to the claims, that the claims are directed to the statutory class of method claims, not composition claims as interpreted by the Examiner. (Office Action at item 10) The Applicant, however, reserves the right to further prosecute claims directed to any compositions presented therein. Withdrawal of these rejections are respectfully requested.

Furthermore, claim 4-7 have been rejected under 35 U.S.C. §112, second paragraph for being indefinite due to antecedent basis issues. (Office Action at item 11) Applicant believes amendments made to the claims address these antecedent basis issues and respectfully request withdrawal of these rejections.

Rejections under 35 USC § 102(a) and (e)

The Examiner has rejected claims 1-10 under 35 USC § 102 (a) and (e) as being anticipated by Block (WO 02/43746), Takahashi et al. (EP 0 613 904), and Noda et al. (EP 0 663 406) because each of these references teaches a species that is covered by the generic peptide in the claims. (Office Action at items 13-18) In light of the amendments to the claims this rejection is respectfully traversed. The Examiner asserts that the Block reference is 102(e) art because the reference and the present application name a common inventor. (Office Action at item 14) While reserving the Applicants' right to rebut the Examiner's assertion that the Block, Takahashi, and Noda references teach peptide species that are generically described by Applicants' generic peptide in the claims, Applicant notes that the Examiner's rejection is improperly based on examination of composition claims and not the method claims elected by the Applicants. Applicant's have clarified by amendment that the claims are directed to the statutory class of method claims.

Inherency – 35 USC § 102(b): The Examiner also states that "[n]either Block, Takahashi et al., or Noda et al. teach that the polypeptides can be used to treat patients suffering from a disease or disorder correlated directly or indirectly with sarcoidosis." However, the Examiner asserts that "[b]ecause the chemical structure of the species taught by Block, Takahashi et al., or Noda et al. is identical to the claimed invention, there is reasonable expectation that the species would meet this additional functional limitation" on the basis that "[t]he discovery and characterization of properties of a known material do not make it novel" under MPEP §2112.

The Examiner states further that " '[p]roducts of identical chemical composition cannot have mutually exclusive properties'. A chemical composition and its properties are inseparable. Therefore if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." Examiner relies on In re Spada, 911 F.2d 705, 709 (Fed. Cir.

1990) for this legal proposition. Also the Examiner shifts the burden of proof to Applicant to show that Applicant's claimed polypeptides possess properties that are not inherently present in the polypeptides taught by Block, Takahashi et al., or Noda et al. Examiner cites In re Fitzgerald, 619, F.2d 67, 205 (CCPA 1980) to support this proposition. We note that the Examiner reviewed the present claims as composition type claims.

The claims at issue before the Federal Circuit Court in In re Spada are composition claims that were held invalid by the Court because the claimed composition was anticipated by a prior patent reference that described the same composition. 911 F.2d at 709. In In re Fitzgerald, the Court of Customs and Patent Appeals found that the rejection of a patent applicant's claims was proper when the applicant failed to show that the product described by the product-by-process claims held properties not inherently present in the prior art. 619 F.2d at 71.

The authority cited by the Examiner supporting the rejection based on inherency does not apply to the present application, because the claims of this application, as amended, are method of use claims, not composition claims nor the product-by-process claims presented in In re Spada and In re Fitzgerald, respectively.

With regard to inherency, the Court of Appeals for the Federal Circuit has held that " '[a] prior art reference may anticipate with out disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference.' " Abbott Laboratories v. Baxter Pharm. Prod., Inc., 471 F.3d 1363, 1368 (Fed. Cir. 2006) citing Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1377 (Fed. Cir. 2003).

However, the Federal Circuit has also held that "[a] new use for an old process or product is patentable if the new use or application is itself not "obvious" to one skilled in the art." Allegheny Drop Forge Co. v. Portec Inc., 541 F.2d 383, 386 (3rd Cir. 1976). The Federal Circuit Court has steadfastly maintained this proposition in Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., wherein the Court stated that "new uses of known processes may be patentable." Bristol-Myers Squibb co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2003); see also Nicholas v. Perricone, 432 F.3d 1368, 1379 (Fed. Cir. 2005) ("[n]ew uses of old products or processes are indeed patentable subject matter"). In support of this proposition, the Federal Circuit cited 35 USC § 101, which states "[w]however invents or discovers any new and useful process ... may obtain a patent therefore. The term 'process' means process, art, or method and includes a new use of a known

process, machine, manufacture, composition of matter, or material." See 246 F.3d 1376.

Thus, "principles of inherency do not prohibit a process patent for a new use of an old structure". 432 F.3d at 1379 citing In re King, 801 F.2d 1324, 1326 (Fed. Cir. 1986); see also Schering Corp. v. Geneva Pharm., Inc., 348 F.3d 992, 994 (Fed. Cir. 2003).

Because "[n]either Block, Takahashi et al., or Noda et al. teach that the polypeptides can be used to treat patients suffering from a disease or disorder correlated directly or indirectly with sarcoidosis"; (Office Action at item 17) Applicant asserts that the cited references, i.e., Block, Takahashi et al., and Noda et al., do not anticipate the presently amended claims, by reason of inherency or otherwise. Assuming *arguendo* that Block, Takahashi et al., and Noda et al. recite the peptide described in Applicant's presently amended claims, it is a well accepted tenant of patent law that a new use of a known product, composition, or process is patentable subject matter if it is not obvious. Because Examiner acknowledges that the cited references do not teach the use of a peptide for treating patients suffering from a disease or disorder correlated directly or indirectly with sarcoidosis, Applicants submit that the presently amended claims are patentable and not anticipated by references cited by Examiner in the outstanding office action. Thus, Applicant respectfully requests withdrawal of these rejections.

Double Patenting Rejection

Claims 1-10 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-8 of copending U.S. Application No. 10/501,660 and claims 1-8, 12, 15 and 18 of copending U.S. Application 10/564,849. Applicant believes that in light of the present claim amendments these provisional rejections are no longer proper.

Applicant notes that, if the "provisional" double patenting rejection is the only rejection remaining in the Application, then the Examiner should withdraw the rejection and permit the Application to issue as a patent. M.P.E.P. §804.

Conclusion

As a result of the foregoing, it is asserted by Applicants that the remaining Claims in the Application are in condition for allowance, and respectfully request an early allowance of such Claims.

Applicants respectfully request that the Examiner call Applicants' agent at the below listed number if the Examiner believes that such a discussion would be helpful in resolving any remaining problems.

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8 November 2007

Respectfully submitted,

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